REMARKS

I. Formal Matters

Claims 41-69 are all the claims pending in the present Application. By this Amendment, Applicants hereby amend claims 55 and 69 for reasons of clarity and precision of language. Additionally, Applicants hereby add claims 70-142, so as to further define the present invention. Support within the specification for the newly added claims 70-142 can be found in the chart attached herein. (Attachment A).

Applicants thank the Examiner for initialing the Information Disclosure Statement filed on June 22, 2007.

II. Statement of Substance of the Interview

Applicants thank Examiners Sievers, Barlow and Lau for the courteous in person Interview on January 23, 2008. An Examiner's Interview Summary Record (PTO-413) was provided to the Applicants. The PTO-413 requires Applicants to file a Statement of Substance of the Interview. The Statement of Substance of the Interview is as follows:

During the Interview, the discussion focused on the Examiner's rejection of claims 41-69 under 35 U.S.C. § 112, first paragraph. In the Office Action of October 9, 2007, Examiner Sievers provided a list of claim terms that required clarification. Applicants' representatives reviewed these claim terms with the Examiners, including the support within the specification for each listed claim term. Examiners Sievers and Lau agreed that each claim term was properly

supported by the specification. Examiner Barlow had a conflicting meeting and was not present during this discussion.

In addition, Applicants' representatives indicated that certain new claims would be added to the Application in the next Response. As such, Applicants' representatives reviewed several proposed new claims with the Examiners, and the support for these new claims as found throughout the specification.

III. Objection to the Specification

The Examiner has objected to the Abstract of the disclosure under MPEP § 608.01(b) for containing more than 150 words. Applicants have amended the abstract and respectfully assert that this rejection is now moot.

The Examiner has also objected to the first line of the specification as containing a scriveners error. Applicants have amended the specification as requested by the Examiner.

IV. Objection to the Drawing

The Examiner has objected to the drawings because FIGS. 9 and 14 are not placed in proper numerical order with the other figures. Applicants respectfully assert that this is not a proper objection to the drawings.

Specifically, 37 C.F.R § 1.84 states that "[t]he different views must be numbered in consecutive Arabic numerals, starting with 1, independent of the numbering of the sheets and, **if possible**, in the order in which they appear on the drawing sheet(s)." In other words, consecutive

numbering of drawings is preferred, but not required. For at least this reason, Applicants respectfully request that the Examiner remove this objection.

V. Objection to the Declaration

The Examiner alleges that the Oath or declaration is defective. Specifically, the Examiner requires an amended oath, which list applications 10/420,057 or 09/667,199 must be submitted in order to claim the benefit of the earlier filing date. Applicants respectfully disagree.

Initially, Applicants note that the present Oath or declaration, as filed, complies with the requirements of 37 C.F.R. § 1.63. That is, there is simply no requirement under 37 C.F.R. § 1.63 of including each domestic application from which the present Application claims a priority. To the extent the Examiner is referring to 37 C.F.R. § 1.63(c)(2), Applicants respectfully assert that this subsection is directed only to foreign priority claims.[1] As such, Applicants respectfully request for the Examiner to withdraw the present objection.

VI. Claim Rejections Under 35 U.S.C. § 112

The Examiner has rejected claims 41-69 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Applicants respectfully note that claims 41-69 were added to the present Application via a preliminary Amendment, filed on June 13, 2007. The MPEP states that when new claims are

[1] (c) … (2)Any **foreign application** for patent (or inventor's certificate) for which a claim for priority is made pursuant to § 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month, and year of its filing.

added to the Application, Applicant should show support in the original disclosure for the new or amended claims. (MPEP § 714.02 and § 2163.06). Applicants have met this burden. In particular, Applicants submitted a chart showing support for each element of the newly added claims, as supported by the original disclosure of the present Application.

Nevertheless, as requested by the Examiner during the Interview of January 23, 2008, Applicants discuss the support found throughout the specification for each claim term identified in the Office Action of October 9, 2007. With regard to any remaining disputed claim terms, Applicants respectfully assert that these claims are adequately described in the specification for reasons analogous to those recited with respect to the specific claim terms below.

1. Sensor Data Module

The Examiner asserts that the "sensor data module" may not be sufficiently described in the present specification. Applicants respectfully disagree. In fact, as discussed during the Interview, to the extent that there are differences between the terms recited in the specification and the terms of the claims, these terms are equivalent for the following reasons.

Specifically, claim 41 recites "a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor."

As described in the specification of the present Application, one example of the "on-skin sensor control unit 44 ... includes at least a portion of the electronic components that operate the

sensor 42 and the analyte monitoring device system 40." Additionally, part of the sensor control unit is a "**a sensor circuit 97 for obtaining signals from and operating the sensor 42** ... and **a processing circuit 109 that, at minimum, obtains signals from the sensor circuit 97**." (Pages 60-61; lines 27 and 1-12).

The specification also teaches that the above-described, or other, embodiments of the analyte monitoring system, for example the sensor control unit "**may be implemented using either software routines, hardware components, or combinations thereof**." (Page 62, lines 15-20). One of ordinary skill in the art would understand that a "module" is simply a generic term for a software routine, or a combination of software and hardware, that accomplishes a desired function, for example, operating the sensor control unit 44. As such, it would be apparent to one of ordinary skill in the art that the function of the sensor control unit 44 can be implemented using a sensor data module.

For at least the above reasons, Applicants respectfully asserts that the "sensor data module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

2. Reference Input Module

The Examiner asserts that the "reference input module" is not described in the specification. Applicants respectfully disagree. To the extent that there are differences between the terms recited in the specification and the terms of the claims, these terms are equivalent for the following reasons.

Claim 41 recites "a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point, … wherein the reference input module is configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold."

The specification of the present Application explains that calibration data may be obtained a plurality of ways. For example, calibration data can be: factory determined and input into the on skin sensor control unit, may be stored in the calibration data storage unit, or the calibration data may be provided based on tests performed by a doctor, or the patient himself using a single point glucose monitor. (Page 72, lines 7-22).

The specification also discloses that: in one embodiment of the present invention, the analyte monitoring system includes a receiver/display unit which is configured not to allow calibration if the rate of change of the signal is above a threshold. Specifically, the specification recites "The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed and if the calibration data is acceptable. The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater); 4) the uncalibrated signal exceeds a threshold maximum value (e.g., 5, 10, 20, or 40 nA) or is below a threshold minimum value (e.g., 0.05, 0.2, 0.5, or 1 nA)." (Page 73; lines 15-27).

As described during the Interview, and set forth with respect to the term "sensor data module" above, it would be apparent to one of ordinary skill in the art that the function of inputting the reference analyte data into the receiver can be implemented using a reference input module.

For at least the above reasons, Applicants respectfully asserts that the "reference input module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

3. Reference Analyte Monitor

The Examiner asserts that the "reference analyte monitor" may not be sufficiently described in the specification. Applicants respectfully disagree.

Claim 41 recites "a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point."

As described above, calibration data may be obtained a plurality of ways. For example, calibration data can be: factory determined and input into the on skin sensor control unit, may be stored in the calibration data storage unit, or the calibration data may be provided based on tests performed by a doctor, or the patient himself using a single point glucose monitor. (Page 72, lines 7-22).

In another embodiment, the receiver/display unit 46, 48 may be integrated with a calibration unit. For example, the receiver/display unit 46, 48 may, include a conventional blood glucose monitor. (Page 89; lines 13-15).

As discussed during the Interview, to the extent that there are differences between the terms used in the specification and the claims, the terms are equivalent. Specifically, it would be obvious to one of ordinary skill in the art that any one of the above means of obtaining analyte data can be considered a reference analyte monitor.

For at least the above reasons, Applicants respectfully asserts that the "reference analyte monitor" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

4. Data Matching Module

With respect to the term "data matching module, as found for example in claim 42, the Examiner also asserts that this term is not adequately described in the specification. Applicants respectfully disagree.

Specifically, claim 42 recites "a data matching module configured to match a reference data point to a sensor data point to form a matched data pair, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained."

As discussed during the Interview, in at least one exemplary embodiment, in order to calibrate the sensor reference data and sensor data are required, wherein the reference data and sensor data is obtained during substantially corresponding times. That is, by virtue of calibrating the sensor using reference data and sensor data, these two pieces of data are "matched." Additionally, as explained throughout the specification, when the single point glucose monitor is built into the receiver, and calibration is needed, the reading from the glucose monitor is automatically transferred to the proper circuits within the receiver to make the calibration happen. (See, Page 89; ll. 13-23)

More specifically, in some embodiments of the invention, calibration data may be required at periodic intervals, for example, every eight hours, once a day, or once a week, to confirm that accurate analyte levels are being reported. Calibration may also be required each time a new sensor 42 is implanted or if the sensor exceeds a threshold minimum or maximum value or if the rate of change in the sensor signal exceeds a threshold value. In some cases, it may be necessary to wait a period of time after the implantation of the sensor 42 before calibrating to allow the sensor 42 to achieve equilibrium. (Page 72; line 26 to Page 73; line 4).

Additionally, "[t]he on-skin sensor control unit 44 and/or receiver display/units 46, 48 may also include an auditory or visual indicator to remind the patient that information, such as analyte levels, reported by the analyte monitoring device 40, **may not be accurate because a calibration of the sensor 42 has not been performed within the predetermined periodic time interval** and/or after implantation of a new sensor 42." (Page 73; lines 9-14). In other words,

calibration should be performed using reference analyte data and sensor data which was obtained at substantially corresponding times.

In this respect, the Examiner has asked for Applicants to define the term "substantially corresponding time" as used in the claim. Applicants respectfully assert that, in certain embodiments, one of ordinary skill in the art would understand that reference analyte data and sensor data should be obtained within a time frame that is determined by the healthcare provider, factory-set, or otherwise determined so as to provide a sufficiently accurate calibration of the sensor signal.

To the extent that there are differences between the terms used in the specification and he claims, Applicants respectfully assert that these terms are equivalent. Specifically, it would be obvious to one of ordinary skill in the art that the above-described functions, for example, comparing the reference and sensor data, could be accomplished using a data matching module.

For at least the above reasons, Applicants respectfully asserts that the "data matching module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

5. Matched Data Pair

With respect to the claimed "matched data pair," the Examiner asserts that this term may not be sufficiently described in the specification. Applicants respectfully disagree for reasons analogous to those recited above with respect to the "data matching module."

Specifically, claim 42 recites that "a data matching module [is] configured to match a reference data point to a sensor data point to form a matched data pair." The result of matching sensor data with the reference analyte data can be described as a "matched data pair." To the extent that there are differences between the terms used in the specification and the claims, Applicants respectfully assert that these terms are equivalent. Specifically, it would be obvious to one of ordinary skill in the art that the comparison of the data obtained from the sensor and the reference input module constitutes a "matched data pair."

For at least the above reasons, Applicants respectfully asserts that the "matched data pair" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

6. Calibration Module

The Examiner also asserts that the "calibration module" may not be sufficiently described in the specification. Applicants respectfully disagree for reasons analogous to those recited above with respect to the "data matching module."

Specifically, claim 43 recites "a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained."

As described in the specification, "[t]he on-skin sensor control unit 44 and/or receiver display/units 46, 48 may also include an auditory or visual indicator to remind the patient that information, such as analyte levels, reported by the analyte monitoring device 40, **may not be accurate because a calibration of the sensor 42 has not been performed within the predetermined periodic time interval** and/or after implantation of a new sensor 42." (Page 73; lines 9-14). Thus, calibration information is formed using reference analyte data and sensor data that was obtained at substantially corresponding times. Additionally, the specification teaches that "[t]he processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed and if the calibration data is acceptable. The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater)." (Page 73; lines 15-26).

Additionally, the present Application also discloses a processing circuit 109 that can determine whether calibration is needed, or if calibration data is acceptable based at least in part on the rate of change of the sensor data stream. (See page 73, lines 15-27). As also described above, the analyte monitoring system and its functions or components "**may be implemented using either software routines, hardware components, or combinations thereof**."

In light of the above, to the extent that there are differences between the terms used in the specification and the claims, the terms are equivalent. Specifically, it would be obvious to one of

ordinary skill in the art that the above-described functions, for example, calibrating the sensor data stream using reference analyte data obtained at a substantially corresponding time, could be accomplished using a calibration module.

For at least the above reasons, Applicants respectfully asserts that the "calibration module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

*7. **Conversion Function Module***

The Examiner also asserts that the "conversion function module" may not be sufficiently described in the specification of the present Application. Applicants respectfully disagree. As discussed during the Interview, to the extent that there are differences between the terms used in the specification and the claims, these terms are equivalent.

Specifically, claim 44 recites "a conversion function module configured to create a conversion function based *at least in part on* at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and wherein the conversion function is configured to convert the sensor data point into a calibrated data point." (emphasis added).

In one embodiment of the present invention, the analyte monitoring system includes a receiver/display unit which is configured not to allow calibration if the rate of change of the signal is below a threshold. Specifically, the specification recites "The processing circuit 109 of

the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed and if the calibration data is acceptable. The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater); 4) the uncalibrated signal exceeds a threshold maximum value (e.g., 5, 10, 20, or 40 nA) or is below a threshold minimum value (e.g., 0.05, 0.2, 0.5, or 1 nA)." (Page 73; lines 15-27).

Additionally, "[t]he analyzer 152 may have a variety of functions, similar to the processor circuit 109 of the on-skin sensor control unit 44, including 1) modifying the signals from the sensor 42 using calibration data and/or measurements from the temperature probe 66." (Page 83; lines 6-9). The specification also notes that these functions can be accomplished using software, hardware, or a combination thereof. (page 62, lines 15-20).

As such, it would be obvious for one of ordinary skill in the art to implement the functions of the receiver/display unit, including the analyzer, using a conversion function module.

For at least the above reasons, Applicants respectfully asserts that the "conversion function module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

8. Sensor Data Transformation Module

The Examiner further asserts that the "sensor data transformation module" may not be sufficiently described in the specification. Applicants respectfully disagree. In fact, as discussed during the Interview, to the extent that there are differences between the terms used in the specification and the claims, the terms are equivalent.

Claim 45 recites "a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a threshold."

As described above with respect to the "conversion function module," in one exemplary embodiment, the analyte monitoring system includes an on-skin sensor control unit which is configured not to allow calibration if the rate of change of the signal is above a threshold rate. As also described above, the receiver/display unit includes an analyzer that modifies, or converts, the signal from the sensor circuit using calibration data. Thus, in the instance that the rate of change of the signal is below a threshold, the analyzer can convert the signal into a calibrated data point. The specification also notes that these functions can be accomplished using software, hardware, or a combination thereof. (page 62, lines 15-20).

In light of the above, it would be obvious for one of ordinary skill in the art to implement the functions of the receiver/display unit, including the analyzer, using a sensor data transformation module.

For at least the above reasons, Applicants respectfully asserts that the "sensor data transformation module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

9. Calibration Evaluation Module

The Examiner also asserts that the "calibration evaluation module" may not be sufficiently described in the specification. Applicants respectfully disagree for reasons analogous to those recited above with respect to the "conversion function module."

As recited in claim 46, "a calibration evaluation module [is] configured to evaluate the matched pair, wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold."

As described above, with respect to the "conversion function module," in one exemplary embodiment, the analyte monitoring system includes an on-skin sensor control unit which is configured not to allow calibration if the rate of change of the signal is above a threshold rate. Additionally, the analyte monitoring system and its functions, or components "may be implemented using either software routines, hardware components, or combinations thereof." (Page 62, lines 15-20). Additionally, the specification teaches that "[t]he processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed and if the calibration data is acceptable. The on-

skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater)." (Page 73; lines 15-26).

As such, and as discussed during the Interview, to the extent that there are differences between the terms used in the specification and the claims, the terms are equivalent. Therefore, it would be obvious for one of ordinary skill in the art to implement the functions of the on-skin sensor control unit using a calibration evaluation module.

For at least the above reasons, Applicants respectfully asserts that the "calibration evaluation module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

10. Clinical Module

With respect to the claimed "clinical module," the Examiner asserts that this term may not be sufficiently described in the specification. Applicants respectfully disagree. As discussed during the Interview, to the extent that there are differences between the terms used in the specification and the claims, the terms are equivalent.

Specifically, independent claim 47 recites that "a clinical module configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable … wherein the first reference data point is

determined to be clinically acceptable if the difference between the first reference data point and the second reference data point is below a threshold."

The specification of the present Application teaches that, in one embodiment of the analyte measurement system, data signals received from one or more working electrode can be used for quality control purposes. For example, "the output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance." (Page 65; lines 4-8). Additionally, in one exemplary embodiment, "using signals from only one working electrode for quality control includes comparing consecutive readings obtained using the single working electrode to determine if they differ by more than a threshold level." (Page 65; lines 21-23). The specification also notes that these functions can be accomplished using software, hardware, or a combination thereof. (page 62, lines 15-20).

As such, it would be obvious for one of ordinary skill in the art to implement the quality control function of the working electrode using a clinical module.

For at least the above reasons, Applicants respectfully asserts that the "clinical module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

11. Stability Module

With respect to the claimed "stability module," the Examiner asserts that this term may not be sufficiently described in the specification. Applicants respectfully disagree. As discussed during the Interview, to the extent that there are differences between the terms used in the specification and the claims, the terms are equivalent.

Specifically, claim 49 recites that "a stability module configured to determine whether the sensor data is stable, wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained."

As described above, with respect to the "conversion function module," in one embodiment, the analyte monitoring system includes an processing circuit or an analyzer, which is configured not to allow calibration if the rate of change of the signal is above a threshold rate. Therefore, if the rate of change of the sensor data signal is acceptable, then calibration is allowed to occur. One of ordinary skill in the art would understand that a signal whose rate of change is does not exceed a threshold rate can be considered "stable." The specification also notes that these functions can be accomplished using software, hardware, or a combination thereof. (Page 62, lines 15-20).

Thus, it would also be obvious to one of ordinary skill in the art to implement the function of the processing circuit or analyzer of the analyte monitoring system using a stability module.

For at least the above reasons, Applicants respectfully asserts that the "stability module" is properly described in the specification, thus complying with the written description requirement under 35 U.S.C. § 112, first paragraph.

VII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

This Application is being filed via the USPTO Electronic Filing System (EFS). Applicants herewith petition the Director of the USPTO to extend the time for reply to the above-identified Office Action for an appropriate length of time if necessary. Any fee due under 37 U.S.C. § 1.17(a) is being paid via the USPTO Electronic Filing System (EFS). The USPTO is also directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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Date: March 7, 2008